



Propoxur CCA Studies

Maija Mizens

to:

Kaitlin Keller

05/25/2011 12:16 PM

Cc:

Kathryn Jakob, Michael Goodis, "bruce.martin.b@bayer.com", Larry Sheets, Steve Spaulding, James McFadden

Hide Details

From: Maija Mizens <MMizens@central.com> Sort List...

To: Kaitlin Keller/DC/USEPA/US@EPA

Cc: Kathryn Jakob/DC/USEPA/US@EPA, Michael Goodis/DC/USEPA/US@EPA, "bruce.martin.b@bayer.com" <bruce.martin.b@bayer.com>, Larry Sheets <larry.sheets@bayer.com>, Steve Spaulding <SSpaulding@central.com>, James McFadden <jmcfadden@central.com>

Dear Kaitlin:

In your correspondence to me earlier this week, you had several questions about the schedule for the CCA studies. WIL Research finalized the schedule for the studies yesterday and answers to you questions are below.

CCA

Time Course

Confirm timing for submission of available time-course data for EPA review (July 2011); & submission of final report. Cholinesterase data from the time course study will be available mid-July and a final report in October 2011. In our previous communication you indicated that the Agency toxicologists would be able to review and comment on the data in about two weeks. I will need any comments by the end of July in order to meet the August start date for the dose range-finding study.

Dose-Response

Confirm timing for submission of available dose-response data (pups & adults) for EPA review; & submission of final report. Has the study schedule been finalized? Yes, the study schedule has been finalized. As noted above the range-finding study will initiate in August with preliminary data available in early October and a final report in January 2012. The dose-response study will be initiated in October with data available in December. The final report is scheduled for the end of March 2012.

Based on your last email regarding the CCA, you indicated that the dose-response portion could begin in August, but that the last of the final reports would likely not be submitted until March 2012. Is there a reason why you anticipate that it will take this length of

time to submit the final reports? EPA toxicologists have suggested that preliminary data is typically available a month or two after the dose-response study is initiated. As noted in the schedule above, reports will take approximately four months to complete, but data will be available earlier.

Are you planning on conducting range-finding studies for pups and adults prior to the initiation of the dose-response study? Yes.

Will you test both pups and adults together, pups only first and then doing only adults, or some combination? The adults will be tested first, followed by the pups.

Submission of preliminary data for review as it becomes available- Do you intend to submit preliminary dose-response data? It would be helpful to receive preliminary data as it becomes available. We can certainly share the data before the reports are completed.

Let me know if you have any other questions or would like to discuss further.

Thank you.

Maija Mizens, PhD, DABT
Director Toxicology
Wellmark International
Central Life Sciences
Phone: 1-847-330-5374
Fax: 1-847-330-5391

Disclaimer: This communication and any attachments contain private, confidential, privileged and/or proprietary information intended solely for the Recipient(s) named above. If you are not the intended Recipient, any use, dissemination, distribution or copying of the communication is strictly prohibited. If received in error, we apologize and ask that you please notify the Sender by returning this e-mail and permanently deleting this communication from your computer, including destruction of any printed copies. Any views expressed herein are not necessarily those of the Company represented by this e-mail source. No contracts, agreements or legally binding understandings may be entered into solely by an e-mail communication